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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/511,582 02/23/00 RAA

J CU-2140 TJK

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HM22/0920

EXAMINER

STUCKER, J

ART UNIT	PAPER NUMBER
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1648

DATE MAILED:

09/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-13 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-13 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is meant by "modulate" in the context of an adjuvant. The term refers to any substance that enhances the potency of an antigen and results in a superior immune response.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for viral vaccines, does not reasonably provide enablement for non-vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not teach modulating (increasing or decreasing) the effect of a substance, only the increase of an immune response to viral vaccination.

There is nothing in the art that would indicate that the claimed adjuvant compound, or similar compounds, would modulate the activity of non-immunogenic compositions. That is, one would expect that this compound, in conjunction with an immunogen would induce an immune response but there is no expectation that the adjuvant would modulate any physiological reaction except enhancing an immune response to an immunogen. There is no support in the specification or the art as to how to make and use the claimed composition for treating allergies and arthritis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-9, 12, and 13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Benach et al.

The instant invention is an adjuvant composition comprised of glucose monomers with β -1,3 and β -1,6 linkages. The specification

discloses that the composition is derived from yeast cell wall and is known as glucan. The phrase "which modulate the effect..." is intended use and does not describe the structure of the claimed compound and is not given patentable weight. This also applies to claims that specifically recited "intended for" or "is administered" with no structural limitations.

Benach et al. teach yeast cell wall derived glucan and its use as an adjuvant. They teach that it is a known, widely applicable adjuvant and has been used for a diverse group of pathogens. See the first column.

Claims 1, 2, 4-9, 12, and 13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Takahashi et al.

Takahashi et al. teach a glucan adjuvant that is administered to fish and crustaceans to immunize them against pathogens. The reference teaches that the compound can be given in food which would administer the compound gastrically. Therefore, the instant invention is anticipated by Takahashi et al.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1 and 3 are rejected under 35 U.S.C. § 103(a) as obvious over Benach et al.

The claimed invention is directed to influenza vaccine compositions. Benach et al. teach that glucan can be used as an adjuvant for viruses. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the formulation of Benach et al. with a well known pathogen such as influenza with the expectation of producing an enhanced influenza vaccine.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rorstad et al. (5,401,727) teach the same yeast extracted glucopyranose polymer adjuvant compound as is instantly claimed and was cited in the specification.

Serial Number: 09/511582
Art Unit: 1648

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No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

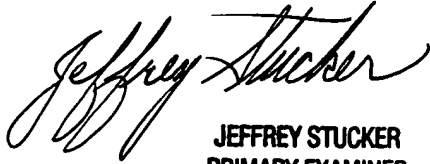
The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JEFFREY STUCKER
PRIMARY EXAMINER